

**California Code of Regulations**  
**Add Title 16 CCR, Division 17**

**§1711. Quality Assurance Programs**

- (a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.
- (b) For purposes of this section, “medication error” means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in this section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient’s agent or any variation allowed by law.
- (c) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form. Unless the pharmacist has already been notified of a medication error by the prescriber or the patient, the pharmacist shall immediately communicate to the patient and the prescriber the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.
- (d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.
- (e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:
  - 1. the date, location, and participants in the quality assurance review;
  - 2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
  - 3. the findings and determinations generated by the quality assurance review; and,
  - 4. recommended changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

- (f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.
- (g) The pharmacy’s compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.
- (h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or

administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

- (i) This section shall become operative on January 14, 2002.

Note:

Authority Cited: Section 4005 of the Business and Professions Code and Section 2 of Chapter 677, Statutes of 2000.

Reference Cited: Section 4125 of the Business and Professions Code.

---

**PATRICIA HARRIS**  
Executive Officer

---

**DATE**